

REMARKS

This is a response to the Office Action dated September 17, 2002. Claims 1-3 and 5-8 are pending in this application. Claims 1-8 have been rejected by the Examiner. As noted above, Applicants have canceled Claims 4 and 9-16 without prejudice, and have amended Claims 1 and 8. The amendments are fully supported by the written description. No new matter has been introduced into the application.

Election/Restrictions

Applicants affirm election of Group I, Claims 1-8. Claims 9-16 have been canceled without prejudice.

Claim Rejections – 35 USC § 112

The Examiner has rejected Claims 1-4 and 8 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have responded as follows:

A. Claim 1

Applicants have amended this claim to read in part, “during an application of the coating substance to the stent.”

B. Claim 3

The Examiner has indicated that it “is unclear whether Applicants intend the coating substance to be a part of the claimed invention.” Applicants have amended Claim 1 to include the coating substance as part of the claimed invention.

C. Claim 4

Claim 4 has been canceled without prejudice.

D. **Claim 8**

Applicants have amended this claim to read in part, “additionally including a temperature modulator.”

As a result of the amendments, Applicants believe that Claims 1-3 and 8 have overcome the rejection. Withdrawal of the rejection and allowance of the claims is respectfully requested. Claim 4 has been canceled without prejudice.

Claim Rejections – 35 USC § 103

A. **Leidner et al. In View of Kawata et al.**

Claims 1-8 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Leidner et al. (USPN 6,056,993) in view of Kawata et al. (USPN 4,932,353). Applicants respectfully submit that the claimed invention has shown superior results which require a finding that the claimed invention was not obvious to one of ordinary skill in the art. Applicants can rebut a *prima facie* case of obviousness by offering evidence of “secondary considerations.” See, *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1965). Rebuttal evidence may include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. See, *In re Dillon*, 919 F.2d 688, 692-93 (Fed. Cir. 1990).

Applicants’ invention addresses a long-felt problem faced when applying compositions to implantable devices such as stents. As noted on page 2 of the Specification, some of the problems that have been associated with coating stents include the formation of polymer “cob webs” between the stent struts, excessive gathering of clumps or “pool webs” of coating on the surface of the stent struts, and lack of uniformity of the coating. Applicants have clearly demonstrated that the claimed invention yields improved properties which alleviate these problems. For example, the Examiner is specifically referred to pages 10 and 11 of the Specification:

By increasing the temperature of the composition during the application of the composition to the stent, unexpected results have been achieved. **Better coating uniformity and properties, such as lack of “cob webs” and “pool webs” have been observed** by raising the temperature of the composition from ambient to between 35°C to 40°C. By raising the temperature of the coating solution, the viscosity, surface energy, atomized droplet size of the solution can be reduced. **Such effects have lead to improved wetting characteristics of the atomized solution on the metallic (e.g., stainless steel) surface of the stent.** Another advantage gained by the apparatus of the present invention is the ability to increase the solid content in the solution, and thus deposit more coating per pass. Deposition of more solid content per pass leads to a reduction in the time of production of the stents

(emphasis added). The Examiner is also referred to Examples 1 and 2 (pages 12-13 of the Specification) which demonstrate that the claimed invention has had superior performance. As shown in Example 1, for instance, even though a drug layer containing 400 micrograms of polymer and drug, and a 400 microgram top coat were deposited on a stent, the stent did not “illustrate any significant formation of “cob webs.” The same results were found for Example 2. Therefore, Applicants have clearly demonstrated that the claimed invention has shown superior results which require a finding that the claimed invention was not obvious to one of ordinary skill in the art. Accordingly, Claims 1-3 and 5-8 are allowable over Leidner et al. in view of Kawata et al. Claim 4 has been canceled without prejudice.

B. Leidner et al. In View of Blackinton

Claims 1-8 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Leidner et al. in view of Blackinton (USPN 4,132,357). As noted above, Applicants have clearly demonstrated that the claimed invention has shown superior results which require a finding that the claimed invention was not obvious to one of ordinary skill in the art. Accordingly, Claims 1-3 and 5-8 are allowable over Leidner et al. in view of Blackinton. Claim 4 has been canceled without prejudice.

C. Ding In View of Blackinton

Claims 1-8 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Ding (USPN 5,980,972) in view of Blackinton. As noted above, Applicants have clearly demonstrated that the claimed invention has shown superior results which require a finding that the claimed invention was not obvious to one of ordinary skill in the art. Accordingly, Claims 1-3 and 5-8 are allowable over Ding in view of Blackinton. Claim 4 has been canceled without prejudice.


CONCLUSION

Claims 1-3 and 5-8 are pending in this application. Examination and allowance of the claims are respectfully requested. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0345.

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Respectfully submitted,

A handwritten signature in black ink, appearing to be 'PJM', is written over a horizontal line.

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Version With Markings To Show Changes Made

IN THE CLAIMS

Please amend the Claims as indicated below. The Italicized claim has not been amended and is provided for the Examiner's convenience.

1. (Amended) An applicator for applying a coating substance to ~~an implantable medical device~~a stent, comprising a nozzle and a temperature controller in thermal communication with the nozzle for adjusting the temperature of ~~the~~a coating substance during ~~the~~an application ~~process~~of the coating substance to the stent.

2. *The applicator of Claim 1, wherein the temperature controller circumscribes the nozzle and is position in close proximity to an orifice of the nozzle through which the coating substance is applied.*

3. *The applicator of Claim 1, wherein the coating substance includes a polymer dissolved in a solvent and optionally a therapeutic substance added thereto.*

Please cancel Claim 4.

5. *An apparatus for applying a composition to a stent, comprising:*
(a) an applicator for spraying a composition at the stent; and
(b) a temperature controller connected to the applicator for adjusting the temperature of the composition to a temperature other than ambient temperature.

6. *The apparatus of Claim 5, wherein the applicator comprises a body extending into a nozzle, such that the temperature controller is positioned in close proximity to the nozzle.*

7. *The apparatus of Claim 5, wherein the applicator is an air-assisted internal or external mixing atomizer.*

8. (Amended) The apparatus of Claim 5, additionally including a temperature ~~modular~~modulator in communication with the temperature controller for maintaining the temperature of the composition at a constant level during ~~the~~an application ~~of the~~
~~composition~~process.